IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A., Plaintiffs, v. MYLAN LABORATORIES LTD. and MYLAN PHARMACEUTICALS INC., Defendants.	HONORABLE JEROME B. SIMANDLE Civil Action Nos. 14-7094 (JBS/JS) 15-1684 (JBS/JS) **MARKMAN OPINION**
BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A., Plaintiffs, v. SAGENT PHARMACEUTICALS INC., Defendant.	

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SIMANDLE, Chief Judge:

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I. INTRODUCTION

These related patent infringement actions under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 282, generally concern the assertions of Plaintiffs Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. (collectively, "**Baxter**") that the proposed generic esmolol hydrochloride

products of Defendants Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc. (hereinafter, "**Mylan**"), and Sagent Pharmaceuticals Inc. (hereinafter, "**Sagent**" and collectively, "**Defendants**")[1] infringe the various patents covering Baxter's esmolol hydrochloride product, U.S. Patent Nos. 6,310,094 (hereinafter, "'094 Patent") and 6,528,540 (hereinafter, "'540 Patent" and collectively, the "patents-in-suit" or "Patents"), a "continuation-in-part" of the '094 Patent.[2]

Following factual and claims construction discovery, the parties now request that the Court construe the following three claim terms:[3]

1. "**Sterile**," as it appears in asserted claims 4 through 9 of the '094 Patent, and claims 6, and 12 through 16 of the '540 Patent;[4]

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[1] Although Defendants seek to market generic esmolol products under different abbreviated new drug applications (hereinafter, "ANDAs"), they jointly briefed the disputed claim terms at issue here.

[2] As a result, the patents-in-suit share essentially identical specifications and disclosures. (Compare '094 Patent, with '540 Patent.) For that reason, the Court will, in the interests of simplicity, primarily cite to the '094 Patent, unless otherwise indicated.

[3] The parties initially sought construction of the claim term "osmotic-adjusting agent," but subsequently stipulated that the Court's construction of "osmotic-adjusting agent" in a related case, Baxter Healthcare Corp. v. HQ Specialty Pharma Corp., ___ F. Supp. 3d ____, No. 13-6228, 2015 WL 5646779, at *6 (D.N.J. Sept. 23, 2015) (hereinafter, the "HQ case"), would govern these actions. [See Docket Item 82 in 14-7094; Docket Item 58 in 15-1684.]

[4] Although Baxter purports to seek construction of only the term "sterile," the definition proposed by Baxter contains two discrete components, and ultimately requires (if adopted) construction of the terms "sterile" and "state of sterility."

2. "**Aqueous**," as it appears in asserted claims 1 through 9 of the '094 Patent, and claims 6, and 12 through 16 of the '540 Patent;[5] and

3. "**Injectable, aqueous pharmaceutical composition**," as it appears in asserted claims 1 through 9 of the '094 Patent.

In seeking construction, Baxter takes the position, on essentially each disputed claim term, that the intrinsic record discloses a specific definition, and/or reflects the patentee's intention that the term be defined by reference to the "ordinary" meaning advanced in its extrinsic sources (namely, expert testimony and dictionary definitions). (See, e.g., Baxter's Opening Br. at 8-23; Baxter's Responsive Br. at 2-20.) More specifically, though, Baxter claims (1) that the inventors acted as their own lexicographer in reciting the term "sterile," (2) intended to incorporate their view on the "ordinary mean" of the term "aqueous," and (3) limited the scope of the phrase "injectable, aqueous pharmaceutical composition" through reference, in the specification, to the characteristics that form the "heart" of Baxter's claimed invention (namely, a stable, ready-to-use composition, capable of being autoclaved). (Baxter's Opening Br. at 8-23; Baxter's Responsive Br. at 2-20.)

[5] Similar to the situation the Court confronts relative to the term "sterile," the parties' positions on the term "aqueous" reflect the need to construe the concept of an "aqueous" pharmaceutical composition, as opposed to simply the term "aqueous."

Defendants, by contrast, largely eschew the need for formal claim construction and submit, in each instance, that the claim terms involve little more than the application of widely accepted meanings to commonly understood words. (See, e.g., Defs' Opening Br. at 5-7, 11, 15-16; Defs.' Responsive Br. at 1, 4, 10, 13.) In other words, Defendants claim that the disputed terms have "self-evident" or "readily apparent" meanings, and argue that Baxter's narrow definitions result from a litigation-driven effort to avoid relevant prior art. (See, e.g., id.) In the event this Court deems construction necessary (as it does), Defendants alternatively advance specific constructions consonant with their view of the intrinsic record of the patents-in-suit. (See, e.g., Defs.' Opening Br. at 7-10, 12-14, 16.)

Despite any nuances in the disclosures of the patents-in-suit, the claim terms at issue here constitute obviously commonplace terms. The primary issue relative to the construction of "sterile" and "injectable, aqueous pharmaceutical composition" concerns whether the patentees ascribed a specific scope to these claim terms, or whether the more general ordinary meaning should prevail. Resolution of the term "aqueous," by contrast, turns, more simply, upon how to characterize the plain and ordinary meaning.

In considering the claim terms, the Court has benefited from extensive briefing and attorney argument at a Markman hearing.[6] For the reasons that follow, the Court construes the disputed claim terms as follows:[7]

Term	Court's Construction
"sterile" and "state of sterility"	a composition that has been brought to a state of sterility and has not been subsequently exposed to microbiological contamination (i.e. the container holding the sterile composition has not been compromised) **-and-** sterility is freedom from live bacteria or other microorganisms
"aqueous" pharmaceutical composition	an "aqueous" pharmaceutical composition is a solution in which water is the solvent
"Injectable, aqueous pharmaceutical composition"	a stable, ready-to-use aqueous parenteral solution

[6] The Court conducted a Markman hearing on March 31, 2016, at which time the Court received a brief technical tutorial, and attorney argument on the disputed claim terms.

[7] The relatively brief record amassed by the parties in connection with the pending Markman submissions includes the parties' briefing, certain extrinsic authority, and the declaration (with exhibits) of Baxter's expert, Steven J. Bannister, Ph.D (hereinafter, "Dr. Bannister").

II. BACKGROUND

A. Factual and Procedural Background

1. Background to Esmolol Hydrochloride and Baxter's Innovative Esmolol Research

Esmolol hydrochloride constitutes one type of "beta-blocker," a class of drugs that block the "beta" receptor of heart muscles, arteries, and certain other tissue. ('094 Patent at 1:13-23.) Within this large class of drugs, however, esmolol proves unique because of its "short-acting" nature, making it "often desirable in the critical care setting to quickly reduce heart work or improve rhythmicity during a cardiac crisis." (Id.)

Baxter, a trailblazer in the esmolol industry, has "'successfully commercialized various esmolol products under its BREVIBLOC® trademark'" for over thirty years. Baxter Healthcare Corp v. HQ Specialty Pharma Corp., ___ F. Supp. 3d ____, No. 13-6228, 2016 WL 344888, at *3 (D.N.J. Jan. 26, 2016) (citations omitted). Early esmolol formulations, however, suffered from "extreme susceptibility to hydrolytic degradation," limited (if any) resilience to sterilization by autoclaving,[8] and dilution errors by the ultimate users (often resulting in patients

[8] As this Court explained in the HQ case, "[a]utoclaving refers to a form of sterilization that subjects a product in its final packaging to a combination of heat and steam for a period of time sufficient to kill any microorganisms." HQ Specialty Pharma Corp., ___ F. Supp. 3d ____, 2016 WL 344888, at *2 n.7 (citation omitted).

receiving an excess dosage of the formulation). ('540 Patent at 1:30-40.) In other words, the prior art esmolol compositions readily broke down in the presence of water, and proved incapable of effective terminal sterilization (requiring that the formulations instead be sterilized aseptically in a "clean" environment). ('094 Patent at 1:40-49; '540 Patent at 2:1-41.)

2. Baxter's Innovative Esmolol Hydrochloride Product, BREVIBLOC®

Through the patents-in-suit, Baxter claims to have solved these problems, and developed a ready-to-use, stable aqueous esmolol formulation capable of sterilization by autoclaving. ('094 Patent at 2:1-14; '540 Patent at 2:1-14.) Indeed, in contrast to the prior art, the claimed formulations prove "stable against hydrolytic degradation and other adverse chemical reactions," and possess "a pharmaceutically-acceptable shelf-life." ('094 Patent at 2:3-5.)

Taken together, Baxter's Patents purport to provide a stable, ready-to-use parenteral solution containing esmolol hydrochloride, a buffering agent, an osmotic-adjusting agent, and methods for preparing the solution in a premixed and injectable form. More specifically, though, the '094 Patent, titled "**READY-TO-USE ESMOLOL SOLUTION**," discloses a ready-to-use injectable, aqueous form of Baxter's esmolol formulation, in a flexible plastic container or intravenous bag (generally

identified in the '094 Patent as an IntraVia™ flexible plastic container). ('094 Patent at Title Page, 1:4-10, 62-65.) The claims of the '094 Patent, in turn, disclose an esmolol composition and a method for preparing that composition. ('094 Patent at Title Page, 5:1-6:24.) Asserted claim 1, for example, speaks in terms of an esmolol composition, and specifically claims (with emphasis for the disputed claim terms):

> An **injectable, aqueous pharmaceutical composition** for the treatment of cardiac conditions, having a pH between 3.5 and 6.5 and comprising:
>
> a. 0.1-100 mg/ml methyl-3-[4-(2-hydroxy-3-isopropylamino) propoxy] phenylpropionate hydrochloride (esmolol hydrochloride),
>
> b. 0.1-5.0 mg/ml buffering agent, and
>
> c. 1-100 mg/ml osmotic-adjusting agent.

('094 Patent at 5:9-16 (emphasis added).)[9] Asserted claim 4, by contrast, recites a method for preparing the composition, and specifically provides (again, with emphasis for the disputed claim terms):

> A method for preparing a **sterile**, **injectable aqueous pharmaceutical composition** for the treatment of cardiac conditions, comprising forming an **aqueous** composition having a pH between 3.5 and 6.5 comprising methyl-3-[4-(2-hydroxy-3-isopropylamino) propoxy] phenylpropionate hydrochloride (esmolol hydrochloride), a buffering agent, and an osmotic-adjusting agent in a sealed container, and autoclaving for a period of time sufficient to render the composition sterile.

[9] Claims 2 and 3 depend upon claim 1.

('094 Patent at 6:1-9 (emphases added).) The '540 Patent then incorporates the disclosures associated with the '094 Patent, and builds upon them, by teaching the ready-to-use bag form of the esmolol formulation, as well as a concentrated esmolol form.[10] Asserted claim 6 of the '540 Patent, for example, teaches an **aqueous**, **sterile** pharmaceutical composition comprised of:

> a. 0.1-100 mg/ml esmolol hydrochloride;
>
> b. 0.01-.5 M buffering agent, and
>
> c. 1-100 mg/ml osmotic-adjusting agent.

('540 Patent at 6:45-50.) Claim 13, in turn, provides (with emphasis for the disputed claim terms):

> A method for preparing an **aqueous**, **sterile** pharmaceutical composition suitable for parenteral administration for the treatment of cardiac conditions, comprising forming an **aqueous** composition having a pH between 3.5 and 6.5 comprising 0.1-500 mg/ml methyl-3-[4-(2-hydroxy-3-isopropylamino) propoxy]phenylpropionate hydrochloride (esmolol hydrochloride), 0.01-2 M buffering agent, and 1-500 mg/ml osmotic-adjusting agent in a sealed container and autoclaving for a period of time sufficient to render the composition sterile.

('540 Patent at 7:7-13 (emphases added).)

Following the issuance of these Patents, the United States Food and Drug Administration (hereinafter, the "FDA"), approved

[10] The '540 Patent issued on March 4, 2003, and identifies itself as a "continuation-in-part" of the '094 Patent, which issued on October 30, 2001. ('540 Patent at 1:5-7.)

Baxter's New Drug Application (hereinafter, "NDA") No. 19-386/S-018 (an supplemental NDA No. 19-386/S-020) for BREVIBLOC® Premixed Injection in 2500mg/250ml IntaVia Containers and BREVIBLOC® Double Strength Premixed Injection 20 mg/mL in 100 mL Containers (together, "the BREVIBLOC® Premixed Injection Products"), and listed the patents-in-suit in its listing of approved drug products (i.e., the so-called Orange Book). (See Baxter's Mylan Am. Compl. at ¶¶ 23-24, 28.)

3. Defendants' Proposed Generic Esmolol Hydrochloride Products and Litigation in this District

In September 2014 (by Mylan) and then January 2015 (by Sagent), Defendants requested FDA approval to sell generic esmolol products in 10 mg/mL and 20 mg/mL dosage forms, prior to the expiration of the patents-in-suit. (See id. at ¶¶ 29-30; Baxter's Sagent Compl. at ¶¶ 30-31.) As a result of these ANDA filings, Baxter filed infringement Complaints in this District, and the pending Markman submissions followed.

III. STANDARD OF REVIEW

A. Claim Construction, Generally[11]

When construing asserted claims, claim terms must ordinarily be given "'their ordinary and accustomed meaning as

[11] The construction of claim terms constitutes a question of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996), and the Court need not follow the parties' proposed constructions. See Marine Polymer Techs., Inc. v. HemCon, Inc., 672 F.3d 1350, 1359 n.4 (Fed. Cir.

understood by one of ordinary skill in the art.'" Shire Dev., LLC v. Watson Pharm., Inc., 787 F.3d 1359, 1364 (Fed. Cir. 2015) (quoting Dow Chem. Co. v. Sumitomo Chem. Co., 257 F.3d 1364, 1372 (Fed. Cir. 2001); citing Phillips v. AWH Corp., 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc)). In determining the ordinary and customary meaning, the intrinsic evidence, "the specification and the prosecution history,"[12] Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc., 731 F.3d 1271, 1276 (Fed. Cir. 2013) (citations omitted), "'may shed'" significant "'contextual light.'" Shire Dev., LLC, 787 F.3d at 1364 (Fed. Cir. 2015) (quoting Aventis Pharm. Inc. v. Amino Chems. Ltd., 715 F.3d 1363, 1373 (Fed. Cir. 2013)); see also Golden Bridge Tech., Inc. v. Apple Inc., 758 F.3d 1362, 1365 (Fed. Cir. 2014) (citing Phillips, 415 F.3d at 1315–17). Indeed, the Federal Circuit has

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2012) (en banc); see also Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, No. 14-1078, 2015 WL 7195222, at *6 n.17 (D.N.J. Nov. 16, 2015) (explaining same).

[12] If the intrinsic evidence fails to disclose the meaning of a term, extrinsic evidence, such as dictionaries and expert testimony, may shed useful light on the appropriate construction of a particular term. Phillips, 415 F.3d at 1318. The Federal Circuit, however, discourages "heavy reliance" upon extrinsic sources because it "risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract," and divorced from the intrinsic evidence. Id. at 1321. Indeed, the Federal Circuit directs courts to "'discount'" extrinsic evidence "'clearly at odds ... with the written record of the patent.'" Shire Dev., LLC, 787 F.3d at 1365 (citations and internal quotation marks omitted). Despite these restrictions, however, extrinsic authorities may prove useful, even necessary, under certain circumstances, as explained below.

repeatedly expressed the view that "'[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'" Shire Dev., LLC, 787 F.3d at 1364 (quoting Phillips, 415 F.3d at 1316); see also Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc., ___ F. Supp. 3d ____, 2015 WL 7195222 (D.N.J. Nov. 16, 2015) (setting forth the same framework for claims construction).

B. Standards for Finding Lexicography and/or Disavowal

As relevant here, though, a patentee may deviate from the plain and ordinary meaning, when it "sets out a definition and acts as his own lexicographer," or unequivocally "disavows" a certain meaning or "the full scope of a claim term" in order to obtain the patent. Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citation omitted); see also Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Though "no magic words" trigger either exception, Hill-Rom Servs. v. Stryker Corp., 755 F.3d 1367, 1373 (Fed. Cir. 2014), the standards for finding lexicography and disavowal prove "'exacting.'" Pacing Techs., LLC v. Garmin Int'l, Inc., 778 F.3d 1021, 1024 (Fed. Cir. 2015) (quoting GE Lighting Solutions, LLC v. AgiLight, Inc., Inc., 750 F.3d 1304, 1309 (Fed. Cir. 2014)).

In order to act as a lexicographer, a patentee must "'clearly set forth a definition of the disputed claim term'" and express a clear intention "'to redefine the term.'" Luminara Worldwide, LLC v. Liown Elecs. Co., ___ F.3d ____, No. 2015-1671, 2016 WL 797925, at *7 (Fed. Cir. 2016) (quoting Thorner, 669 F.3d at 1365 (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002))). In other words, the patentee must make plain, through the specification, its intention to define the term in specific way, and apart from the ordinary meaning. See id. (quoting Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008); citing Kara Tech. Inc. v. Stamps.com, 582 F.3d 1341, 1347–48 (Fed. Cir. 2009)); see also C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (noting that the "inventor's written description of the invention" may prove "relevant and controlling insofar as it provides clear lexicography").

Disavowal, by contrast, requires that the specification or prosecution history "'make[] clear that the invention'" does not include "'a particular feature.'" Pacing, 778 F.3d at 1024 (quoting SciMed Life, 242 F.3d at 1341). The Federal Circuit has found that the patentee deviated from the ordinary meaning based upon phrases like, "'the present invention includes...' or 'the present invention is...' or 'all embodiments of the present

invention are....,'" or where the specification "'requires'" a particular step or identifies a specific feature as "'important'" to the overall invention. Id. (citations omitted). In those circumstances, the applicant "alerts the reader" to a narrowed scope of the invention, id. (citation omitted), "'even though the language of the claims, read without reference to the specification," might otherwise support a broader construction. Thorner, 669 F.3d at 1366 (quoting SciMed Life, 242 F.3d at 1341).

Absent lexicography or disavowal, courts "do not depart from the plain meaning of the claims." Luminara Worldwide, LLC, ___ F.3d ____, 2016 WL 797925, at *7 (citation omitted); see also Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004) (explaining that the patentee should ordinarily receive the benefit of "the full scope of its claim language").

IV. DISCUSSION

The parties, as stated above, request construction of the following claim terms: (1) "sterile," (2) "aqueous," and "injectable, aqueous pharmaceutical composition."

A. Defendants' No Construction Approach

Prior to turning to the merits of the parties' positions, the Court addresses one introductory deficiency common to each of Defendants' claims construction positions. More

specifically, the Court rejects, at the outset, the notion that the disputed claim terms require no construction, or can be construed simply by reference, without explanation, to the "plain and ordinary meaning." (See, e.g., Defs.' Opening Br. at 5, 11, & 15; Defs.' Responsive Br. at 1.) Indeed, "[w]hen the parties present a fundamental dispute regarding the scope of a claim term," even an ordinary one, this Court has a "duty to resolve it." O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd., 521 F.3d 1351, 1362 (Fed. Cir. 2008).

The claims construction arguments advanced here plainly demonstrate the parties' fundamental disagreement on the appropriate meaning of the disputed claim terms. Indeed, the parties devoted ample attention in their briefing to the appropriate definitions, and the claim terms themselves form, at least in part, the fundamental fabric of Baxter's claimed invention. In that way, reliance upon the phrase "plain and ordinary meaning," or a determination that the claim terms require "no construction," would offer little in terms of facilitating a resolution of these related actions. Stated differently, a blanket resort to the "'ordinary'" meaning of the disputed claim terms would leave unresolved the parties' disputes, and would largely negate the importance of the claims construction process – a phase of patent litigation specifically directed at determining claim scope in view of the patents-in-

suit. See id. (explaining that "[a] determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning [would] not resolve the parties' dispute").

As a result, the Court concludes that the terms at issue here, though ordinary, require meaningful construction, irrespective of the simplicity of this Court's ultimate constructions.[13] See id. (explaining that courts routinely construe "'ordinary' words," and remanding the case for consideration, in the first instance, of the appropriate construction of the term "only if"); compare ActiveVideo Networks v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1326 (Fed. Cir. 2012) (finding no error in the district court's decision that the disputed terms required no construction, because the plaintiff's "proposed construction erroneously read[] limitations into the claims," and the district court "rejected that construction and [therefore] resolved the dispute between the parties").

[13] For that reason, in the charts that follow, the Court will strikethrough this portion of Defendants' proposed constructions.

With that prefatory determination, the Court turns to the parties' substantive positions relative to each disputed claim term.

B. "Sterile" and "State of Sterility"

Baxter's Patents aim, overall, to provide an "aqueous, sterile pharmaceutical composition ... for the treatment of cardiac conditions," and specifically to disclose the inventors' discovery of ready-to-use and concentrated esmolol formulations capable of withstanding terminal sterilization by autoclaving. ('094 Patent at 2:1-14 (emphasis added), 5:9-10; see also '540 Patent at 2:1-14.)

In terms of defining "sterile," the parties advance the following competing constructions:

Baxter's Proposed Construction	Defendants' Proposed Construction
a composition that has been brought to a state of sterility and has not been subsequently exposed to microbiological contamination (i.e. the container holding the sterile composition has not been compromised) **-and-** sterility is freedom from live bacteria or other microorganisms	~~Plain and ordinary meaning~~ **-or-** having a reduced microbial burden (can be achieved through aseptic processing, autoclaving, etc.)

More specifically, Baxter points to the specification of the '540 Patent, and claims that the "express definition" stated

in the specification governs the construction of the patents-in-suit (including the earlier-filed '094 Patent), and embodies, in any event, "the ordinary meaning of the term 'sterile' in the context of pharmaceutical compositions." (Baxter's Responsive Br. at 4-11.) From this "express definition," though, Baxter then asks the Court to determine that the phrase "state of sterility" connotes, in the ordinary sense, a composition free "of live bacteria or other micoorganisms." (Id. at 7-9.)

Defendants argue, by contrast, that Baxter's proposed construction finds no footing in the specification of the '094 Patent, and that no case law supports the notion that a "selective quote" from the later-in-time '540 Patent can be applied to the construction of the earlier-issued '094 Patent. (Defs.' Responsive Br. at 6-8.) Even more, Defendants argue that Baxter's construction needlessly creates ambiguity by interweaving concepts without "basis in the intrinsic record of either patent-in-suit." (Id. at 7-8.) As a result, Defendants urge the Court to adopt their narrow construction, which they claim better represents the aspects of the specification directed at the concept of "sterile."[14] (See id. at 9.)

[14] During the Markman hearing, counsel for Defendants attempted to cast doubt upon Baxter's current construction, in light of its "ever-changing" construction position in this and the related HQ matter. Even if Baxter proposed a more narrow construction in the Joint Claim Construction Statement in this or the related HQ case, this Court has never construed the term

1. The Patentees Acted as their own Lexicographers

The Court begins with the essentially unremarkable observation that the '094 Patent provides, standing alone, no information from which to divine the meaning of the term "sterile." Indeed, "sterile" appears only in asserted claim 4, and the specification sheds no contextual light on the patentees' intention relative to the disputed term. ('094 Patent at 6:1-9 (describing a "method of preparing a sterile, injectable aqueous pharmaceutical composition" that has, among other things, been "autoclave[ed] for a period of time sufficient to render the composition sterile").) The asserted claims of the '540 Patent similarly add little to the story, and provide no point of reference for the concept of "sterile." (See generally '540 Patent at 5:55-8:11.)

The specification of the '540 Patent, though, which Baxter built upon the '094 Patent, explains in unequivocal terms that,

> **A "sterile" composition, as used in the context of this application, means a composition that has been brought to a state of sterility and has not been subsequently exposed to microbiological contamination, i.e. the container holding the sterile composition has not been compromised**. Sterile compositions are generally prepared by pharmaceutical manufacturers in accordance with current Good Manufacturing Practice

"sterile," and can find no fault in the position Baxter advances here. Nor, in any event, can the Court find Baxter's earlier positions so inconsistent with the present position that Baxter should somehow be bound to, or estopped by, its prior expressions.

> ("cGMP") regulations of the U.S. Food and Drug Administration.

('540 Patent at 2:20-29 (emphasis added).) The issue therefore becomes whether the patentees expressly defined the concept of "sterile" through this portion of the specification.

In order to act as a lexicographer (a position Baxter advances here), the patentee must, as explained above, "clearly set forth a definition of the disputed claim term" and express a clear intention "to define the term." Thorner, 669 F.3d at 1365. The relevant provisions of the specification here, though, prove remarkably clear, and squarely demonstrate lexicography.

Indeed, the syntax of the specification alone supports the view that the patentees intended to express a definition, because it breaks off the term "sterile" with quotes, and does so only in this instance. ('540 Patent at 2:20.) The substance of the specification, in turn, completes the definitional picture, by indicating that "'sterile' ... as used in the context of th[e] application, means..." (Id. at 2:20-21 (emphasis added).) What follows then describes the concept of a "'sterile' composition" as one "that has been brought to state of sterility and has not been subsequently exposed to microbiological contamination, i.e. the container holding the

sterile composition has not been compromised."[15] (Id. at 2:20-25.) In other words, the language of the specification—the "present invention" together with an expressly limited definition of "sterile" as "used in the context of" the '540 Patent—discloses a clear intention that the patentees intended, and indeed did, provide a special definition for the term "sterile."[16] This lexicography, in turn, "must govern the claim construction analysis," Braintree Labs., Inc. v. Novel Labs., Inc., 749 F.3d 1349, 1356 (Fed. Cir. 2014), cert. denied, 135 S.

[15] The specification then explains that, in order to validate sterility, a preparer should look to the "current Good Manufacturing Practice ("cGMP") regulations of the U.S. Food and Drug Administration." ('540 Patent at 2:25-29.) During the Markman hearing, Defendants proposed that this provision be read as an extension of the definition of "sterile." The language of the disclosure itself, though, speaks to the recommended validation techniques for sterility, and not the definition of "sterile."

[16] Defendants quarrel with the express definition contained within the specification, in part, on the grounds that the definition proves unhelpful, because it circularly defines "'sterile'" by reference to a state of "'sterility.'" (Defs.' Responsive Br. at 7 (citations omitted).) Nevertheless, a patentee defines the scope of the claimed invention, and one that acts as a lexicographer retains the ability to ascribe express meanings to its claim terms. For that reason, a patentee's lexicography, circular or otherwise, "governs," Phillips, 415 F3d at 1316, particularly here where the Court will continue on to the phrase "state of sterility." Aside from these circumstances, Defendants' position relies upon cases that rejected "'ambiguous'" or unhelpful constructions, where the relevant patents, unlike here, contained no indication of lexicography. (Defs.' Responsive Br. at 7 (citing L'Oreal S.A. v. Johnson & Johnson Consumer Cos., No. 12-98, 2013 WL 3788803, at *1 n.6 (D. Del. July 19, 2013); Invensas Corp. v. Renesas Elecs. Corp., No. 11-448, 2013 WL 3753621, at *1 n.1 (D. Del. July 15, 2013).)

Ct. 764 (2014), and will be adopted here relative, at a minimum, to the '540 Patent.[17] See also Phillips, 415 F.3d at 1316 (explaining that "the inventor's lexicography governs"); Astrazeneca AB, Akteibolaget Hassle, KBI-E, Inc. v. Mutual Pharma. Co., Inc., 384 F.3d 1333, 1338-41 (Fed. Cir. 2004) (reversing the district court's claim construction, based upon its failure to adopt the express definition provided in the specification); Marktek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1379-81 (Fed. Cir. 2009) (same).

For all of these reasons, the Court construes the term "sterile," consistent with the express definition in the specification of the '540 Patent, to mean "a composition that has been brought to a state of sterility and has not been subsequently exposed to microbiological contamination (i.e. the container holding the sterile composition has not been compromised)." The Court therefore turns to the next step of Baxter's proposed construction – defining the phrase "state of sterility."

2. Defining "State of Sterility"

On this issue, too, the parties stake out different positions, with Baxter claiming that sterility implies "freedom from live bacteria or other microorganisms" (Baxter's Responsive

[17] In Section IV.B.3, the Court addresses whether this express definition should also apply to the earlier-in-time '094 Patent.

Br. at 6-9), while Defendants argue that sterility requires only a "reduced microbial burden." (Defs.' Responsive Br. at 4-9.)

The '540 Patent and its predecessor the '094 Patent, generally teach a pharmaceutically safe, or "sterile," esmolol formulation, as compared to the more contaminant-prone prior art formulations (due to the necessary dilution and aseptic handling). (See, e.g., '540 patent at 1:54-55, 2:6-11, 34-35.) The specification of the '540 Patent, however, fails to convey a uniform understanding of the concept of "sterility." Indeed, the disclosure begins by referring to the concept of "terminal sterilization ... as a way of reducing microbiological burden" and ensuring "the safety of the finished product." (Id. at 1:55-58 (emphasis added).) The patentee then reinforces this interpretation of sterility in the detailed description by stating that the claimed composition can be "subjected to terminal sterilization via autoclaving to reduce the microbiological burden of the formulation." (Id. at 2:7-9 (emphasis added).) In that way, the specification, at least in these provisions, creates the arguable impression that the prescribed sterilization technique (autoclaving or otherwise) serves only to reduce the potential microbiological presence (and not to free it, entirely, from any live bacteria).

Latter portions of the detailed description, however, explain that the preferred terminal sterilization method

"eliminates the risk of microbiological contamination during aseptic handling" (id. at 2:34-35 (emphasis added)), and reflect that sterilization should be used "to destroy all microorganisms within the final, sealed package containing the esmolol formulation." (Id. at 3:53-54.) These disclosures, by contrast, suggest that the claimed composition will be sterilized in a way that reduces the product to a state free from microbiological contaminants (as opposed to a state of reduced microbiological presence).

In other words, the written disclosure lends some credence to the view that sterility could refer to a freedom from microbiological contamination or simply to reduced microbiological contamination. Given the ambiguity in the intrinsic record, the Court turns, as it must, to extrinsic sources in order to determine the ordinary meaning of the concept of sterility.[18] See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 711 F.3d 1348, 1360 (Fed. Cir. 2013) (citations omitted) (explaining that district courts may "rely on extrinsic evidence," when presented with an "ambiguous" intrinsic record). The array of identified

[18] Although Defendants argue that their proposed construction embodies the ordinary meaning of "sterility," Defendants have buttressed their position with no expert opinion and few extrinsic sources. For that reason, the Court looks, as it must, primarily to the extrinsic sources and expert opinion provided by Baxter.

extrinsic authorities uniformly embrace Baxter's view that sterility means freedom from live bacteria or other microorganisms. (See, e.g., Exs. 7-9 to Goldberg Opening Dec.) Indeed, the chapter of "Sterilization" from *Remington: The Science and Practice of Pharmacy* defines sterility as "[t]he absence of viable microogranisms," and explains that sterilization aims "to destroy or eliminate microorganisms." (Ex. 7 to Goldberg Opening Dec. at 753.) The *United States Pharmacopeia*, the sole extrinsic source cited by Defendants, similarly describes "the strictest definition of sterility ... [as a] complete absence of viable microorganisms..." (Ex. B to Devine Responsive Dec. at 1976.) *Webster's Third New International Dictionary* and the *American Heritage College Dictionary* then consistently define sterile as "free" from live bacteria or other microorganisms. (Ex. 8 to Goldberg Opening Dec. at 2238; Ex. 9 to Goldberg Opening Dec. at 1332.)

Aside from these technical sources, Baxter's expert, Dr. Bannister, convincingly explains that a "sterile, injectable pharmaceutical product," as claimed in the patents-in-suit, must have "a zero microbiological burden," because "any microbiological contamination of an injected product would introduce a risk of infection to the patient." (Bannister Opening Dec. at ¶ 60 (emphasis in original).) As a result, Dr. Bannister states his view that the ordinary artisan would

understand the term "state of sterility" to mean "the freedom from live bacteria or other microorganisms."[19] (Bannister Opening Dec. at ¶¶ 52, 57; see also Bannister Responsive Dec. at ¶¶ 2, 13.)

In light of the uniformity exhibited in these extrinsic sources on the ordinary meaning of "sterility," the Court will construe "sterility" to mean "the freedom from live bacteria or other microogranisms."[20]

3. The Express Definition Embodied in the '540 Patent Carries to the '094 Patent

With this conclusion, the question becomes whether the express definition embodied in the '540 Patent can be imputed to the earlier-issued '094 Patent. Nevertheless, because the patents-in-suit share an indisputably familial and related

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[19] Defendants take exception with this construction, based upon the observation in the *United States Pharmacopeia* that "[a]bsolute sterility cannot be practically demonstrated without complete destruction of every finished article." (Defs.' Responsive Br. at 5 (citation omitted).) Despite this prefatory observation, the *United States Pharmacopeia* explains in a later chapter (and in a later and still relevant edition) that tests of sterility require the observation of "no microbial growth" (Ex. 17 to Goldberg Responsive Dec. at 1818-19, 1823), and Defendants have provided no expert opinion for their position that this construction embodies an impractical standard.

[20] During the Markman hearing, Defendants argued that this construction conflicts with the specification and claims of the '540 Patent, because it prohibits dilution of the concentrated esmolol formulation. The claims of the '540 Patent, however, cover the concentrated and diluted esmolol solutions as prepared and packaged in the flexible plastic container or ampule. Thus, the Court finds nothing inconsistent with having the concentrated esmolol form be sterile.

relationship (and indeed the same inventors), this inquiry requires no complex analysis. Indeed, the Federal Circuit has defined it as "standard practice during litigation to review related patents ... to evaluate possible claims constructions," Rosebud LMS Inc. v. Adobe Sys. Inc., 812 F.3d 1070, 1076 (Fed. Cir. 2016), and has specifically instructed district courts to construe claim terms consistently across related patents. See, e.g., NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005) ("Because [plaintiff's] patents all derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents;" courts draw distinctions between related patents for claim construction purposes "only where necessary"); Capital Mach. Co. v. Miller Veneers, Inc., 524 F. App'x. 644, 647 (Fed. Cir. 2014) (generally explaining that claims term in related patents should be construed consistently across related patents); Boss Indus., Inc. v. Yamaha Motor Corp., U.S.A., Inc., 333 F. App'x. 531, 536-37 (Fed. Cir. 2009) ("because each patent-in-suit is derived from the same parent application and shares many common terms with its sister patent, the district court correctly interpreted 'base station' consistently across all of the asserted patents").

Despite these principles, Defendants deem any look-through construction illogical, because an ordinary artisan "would not

and could not know to wait for the issuance of a later-in-time patent [in order to] provide a definition of a given claim term (unless the [ordinary artisan] had a time machine)." (Defs.' Responsive Br. at 6-7.) Defendants, however, have identified no authority for their position that related patents can only be construed consistently from the earlier-issued patent to the later-in-time patent, and not in reverse. Beyond this, in Microsoft Corp. v. Multi-Tech System, Inc., 357 F.3d 1340 (Fed. Cir. 2004) and Capital Machine Co. v. Miller Veneers, Inc., 524 F. App'x. 644 (Fed. Cir. 2014), the Federal Circuit expressly recognized that another form of intrinsic evidence – the prosecution history – could be used to interpret "the same term in both later-issued and earlier-issued patents in the same family." Capital Mach. Co., 524 F. App'x at 649 (citing Microsoft Corp., 357 F.3d at 1350). Indeed, in Capital Machine Co., the Federal Circuit determined that the patentee's "disclaimer of [claim] scope during prosecution of some of the [later-issued] patents-in-suit" applied "equally to limit the [claim term] in the other patents-in-suit," including those that issued earlier. Id. Although Capital Machine Co. addressed itself to portions of the prosecution history, its essential premise – that portions of the intrinsic record in a later-issued patent can be used to interpret the same term in the earlier-issued, related patent – applies equally here,

particularly because the ’094 Patent includes essentially identical teachings on the importance of contaminant-free esmolol solutions. See id.; see also Covidien LP v. Advanced Skeletal Innovations LLC, 81 F. Supp. 3d 27, 36 (D.D.C. 2015) (following Capital Mach. Co. for this premise).

Beyond this, the chronologic sequence of the patents-in-suit demonstrate that the circumstances presented here do not implicate whatever objection Defendants could mount to backfilling an earlier patent with the consistent disclosures of a later-issued patent. Indeed, the ’094 Patent issued on October 30, 2001, and the patentees filed their application for what ultimately became the ’540 Patent on the very same day. This temporal proximity, in turn, diminishes any suggestion that the cross-application of the Patents’ disclosures might somehow allow Baxter to benefit from any deficiency in the earlier disclosures of the ’094 Patent. Indeed, common sense suggests that identical inventors, as here, may choose to augment or further clarify their disclosures in connection with a continuation-in-part patent, particularly where, as here, the patents contain essentially identical relevant teachings.

Finally, as a continuation-in-part of the ’094 Patent, the ’540 Patent has “the same effect, as to such invention, as though filed on the date of the prior application.” 35 U.S.C. § 120. In other words, the ’540 Patent, in essence, “benefit[s]

[from] the filing date of the earlier filed application," here, the '094 Patent, as to common subject matter.[21] Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 556 (Fed. Cir. 1994) (discussing 35 U.S.C. § 120 in connection with continuation patents). Stated differently, 35 U.S.C. § 120 and interpretative case law require that courts view the continuation patent as "part of the same transaction" and as "constituting one continuous application." Id. (citation omitted). This circumstance, in turn, provides additional support for a common interpretation across the patents-in-suit, despite the fact that the Court's construction derives from the definition expressed in the technically later-filed '540 Patent.

Against that backdrop, the Court finds it entirely appropriate, and perhaps necessary, to look to the intrinsic evidence of a later issued, related patent in order to interpret a common term used in both patents. The express definition embodied in the '540 Patent therefore governs the Court's construction of the term "sterile" across the related patents-in-suit.

For all of these reasons, for purposes of the '094 and '540 Patents, the Court construes the term "sterile" to mean "a

[21] The parties do not dispute that the notion of a "sterile" composition constitutes common subject matter to the patents-in-suit. (Compare '094 Patent at 6:1-9, with '540 Patent at 2:20-29.)

composition that has been brought to a state of sterility and has not been subsequently exposed to microbiological contamination (i.e. the container holding the sterile composition has not been compromised)" and the term "state of sterility" to mean "freedom from live bacteria or other microorganisms."

C. "Aqueous" pharmaceutical composition

With respect to the claim term "aqueous," the parties agree that this commonly-understood term should be construed in accordance with its ordinary meaning, but diverge on the actual plain and ordinary meaning.

More specifically, in terms of defining "aqueous," the parties advance the following closely-matched constructions:

Baxter's Proposed Construction	Defendants' Proposed Construction
an "aqueous" composition is a solution in which water is the solvent	~~Plain and ordinary meaning~~ **-or-** containing water

Despite their varied construction, Defendants substantively agree that the ordinary meaning of "aqueous," as recited in the patents-in-suit, includes, at a minimum, the concept of a solution containing water, or an aqueous solution. More simply, despite their claims construction position, Defendants do not genuinely dispute that the claimed compositions are best

characterized as solutions (either in a diluted or concentrated form).

Indeed, Defendants describe the patents-in-suit as providing "a stable, ready-to-use parenteral solution containing esmolol hydrochloride, and methods for preparing those solutions," (Defs.' Opening Br. at 2 (emphases added)), and then cite to extrinsic technical authorities (from the relevant period) that uniformly define "aqueous" as a "[w]ater solution" or "solution[] containing water." (Defs.' Opening Br. at 13 (citing Ex. A to Devine Dec. at 126 (reproducing relevant pages from the *Concise Chemical and Technical Dictionary*); Ex. B to Devine Dec. at 142 (reproducing relevant pages from the *Academic Press Dictionary of Science and Technology*)).)

Beyond this essential agreement, the term "aqueous" as used in the asserted claims, modifies "pharmaceutical composition" ('094 Patent at 5:9), and "a solution[] in which the active ingredient has been dissolved in a liquid" constitutes "the most common form of pharmaceutical composition used for products intended for injection into the bloodstream," like the BREVIBLOC® Premixed Injection Products.[22] (Bannister Opening Dec. at ¶ 63.)

[22] During the Markman hearing, Defendants took issue with Dr. Bannister's opinion, on the grounds that he provided little more than conclusory and unsupported assertions concerning the definition of the claim term "aqueous." Dr. Bannister's opinions, of course, cannot override the plain claim language. See Phillips, 415 F.3d at 1318 (generally explaining that

Consistent with that common understanding, the patents-in-suit tout, overall, pharmaceutical compositions comprised of aqueous, or water-based, solutions of esmolol hydrochloride. (See, e.g., '094 patent at Title ("Ready-to-use Esmolol Solution"); id. at 1:62-2:1 ("The present invention provides a stable, ready-to-use parenteral solution containing esmolol hydrochloride and a pharmaceutically acceptable buffering agent and an osmotic adjusting agent to adjust the tonicity of the solution."); id. at 2:64-5:6 (describing the various preparations/formulations of the esmolol hydrochloride solution, with water for injection); '540 Patent at 2:3-6 ("The present invention provides a stable, ready-to-use parenteral composition containing esmolol hydrochloride and a pharmaceutically acceptable buffering agent and an osmotic adjusting agent to adjust the tonicity of the solution."); id. at 4:15-5:53 (describing the various

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"conclusory, unsupported assertions by experts as to the definition of a claim term" prove unreliable in claims construction). The opinions of Dr. Bannister at issue here, though, prove entirely consistent with the intrinsic record, and help establish the meaning of the term "aqueous" in the particular pharmaceutical field. (See generally Bannister Opening Dec. at ¶¶ 62-74; Bannister Responsive Dec. at ¶¶ 18-26.) Because the parties here seek to construe the term "aqueous" in accordance with its plain and ordinary meaning, the Court rightly refers to Dr. Bannister's opinions in determining the appropriate construction. See Phillips, 415 F.3d at 1318 (citations omitted) (explaining, by contrast, that expert testimony "can be useful to a court" and relied upon "to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field").

preparations/formulations of the esmolol hydrochloride solution, with water for injection).) In other words, the specifications plainly disclose that Baxter's esmolol compositions consist of a solution containing, among other ingredients, water.

Against that backdrop, resolution of the parties' disagreement on the term "aqueous" ultimately hinges upon whether the term "aqueous" pharmaceutical composition means a solution in which water serves as a solvent (as advanced by Baxter), or simply one containing some amount of water for an undefined purpose (as advanced by Defendants). (Compare Baxter's Responsive Br. at 12-16, with Defendants' Responsive Br. at 10-13.) More specifically, Baxter urges the Court to define the term by reference to its purported purpose in the overall esmolol formulation; while, Defendants argue that the term should be construed more simply as referring to a solution containing water. On this issue, though, the Court finds Baxter's position better aligned with the relevant intrinsic record and extrinsic authorities.

The Court begins, again, by noting that the asserted claims themselves provide little guidance on the intended construction of the term "aqueous" pharmaceutical composition for purposes of the patents-in-suit. Rather, the asserted claims 1 and 4 of the '094 Patent merely disclose an "injectable, aqueous pharmaceutical composition for the treatment of cardiac

conditions" ('094 Patent at 5:9-11), and a "method for preparing a sterile, injectable aqueous pharmaceutical composition for the treatment of cardiac conditions." (Id. at 6:1-3.) The asserted claims of the '540 Patent, in turn, teach only an "aqueous, sterile pharmaceutical composition suitable for parenteral administration for the treatment of cardiac conditions." ('540 Patent at 5:61-63, 6:65-67.)

The specifications, though, create the clear impression that the claimed solution consists of one in which water acts as a solvent, or the liquid into which the inventions' other ingredients have been dissolved. More specifically, the disclosures of the patents-in-suit describe formulations comprised of (1) esmolol hydrochloride, (2) a buffering agent, (3) an osmotic-adjusting agent, and (4) a pH adjuster. (See '094 Patent at 1:4-10; '540 Patent at 2:3-6.) The three exemplary compositions in the specifications, in turn, list preparations consisting of specific quantities of (1) esmolol hydrochloride, (2) sodium chloride and/or dextrose (as two of the claimed osmotic-adjusting agents), (3) sodium acetate trihydrate and/or glacial acetic acid (as two of the possible buffering agents), (4) sodium hydroxide/hydrochloric acid (for pH adjustment), and (5) water for injection. (See '094 Patent at 1:4-10; '540 Patent at 2:3-6.) Example 1 then adds further

detail to the process of combining the ingredients,[23] and generally discloses a process in which the preparer collects "[e]ighty percent (80%) of the final volume of cool Water for Injection ... in a calibrated compounding tank," and slowly adds each individual excipient (namely, sodium chloride, glacial acetic acid, sodium acetate, and esmolol hydrochloride) to the tank until dissolved.[24] ('094 Patent at 3:47-62; '540 Patent at 4:34-49.) In other words, the exemplary embodiments teach a composition in which water performs a solvent function, particularly when viewed through the lens of the Patents' overall disclosure of an aqueous esmolol composition.[25] Against

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[23] Examples 2 and 3 then repeat the process described in Example 1, but with slight variations in the quantities of certain excipients.

[24] Example 1 describes various phases of preparation beginning from a water base, becoming a "buffer solution" after inclusion of sodium chloride, glacial acetic acid, and sodium acetate, and finally forming a "slurry solution" following the addition of esmolol hydrochloride. ('094 Patent at 3:47-62.) Based upon this spectrum of solutions, Defendants essentially claim that these other ingredients qualify as co-solvents. Nevertheless, the specifications reflect, as stated below, that these excipients perform distinct, non-solvent functions in the claimed inventions (as either a buffering agent or an osmotic-adjusting agent), and so the Court finds Defendants' position unconvincing.

[25] This can be contrasted to a prior art reference to the '540 Patent, U.S. Patent No. 5,017,609 (mistakenly referred as U.S. Patent No. 5,107,609) (hereinafter, the "'609 Patent", which the patentees describe as "disclos[ing] a concentrated formulation ... containing esmolol in an aqueous buffer solution, with propylene glycol and ethanol added to increase solubility of the esmolol." ('540 Patent at 1:45-48.) In other words, because the '609 Patent formulation used propylene glycol and ethanol to increase the solubility of the composition, the patentees

that backdrop, Dr. Bannister explains that a person of ordinary skill in the art would understand that an "aqueous" pharmaceutical composition, as used in the patents-in-suit, means "a solution in which water is the solvent."[26] (Bannister

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characterized the formulation as an "an aqueous buffer solution," rather than an "aqueous" composition, as claimed by the patents-in-suit. (Id.) This contrast, in turn, supports the view that "aqueous" pharmaceutical compositions does not, in the ordinary sense, refer to compositions that use co-solvents in addition to water. (See Bannister Responsive Dec. at ¶¶ 23-24.)

[26] Defendants argue against any construction of water as "'the' sole solvent," based upon their belief that glacial acetic acids acts as a co-solvent in at least some of the exemplary formulations, and because such a construction purportedly "obfuscates, rather than clarifies the meaning of the claim term." (Defs.' Opening Br. at 14 (emphasis in original).) More specifically, as to their position on the claimed formulations containing solvents other than water, Defendants point to the claim language that identifies glacial acetic acid (or, acetate) as a buffering agent, then to the claims that describe the aqueous pharmaceutical composition as being comprised, in part, of 0.1-5.0 mg/mL buffering agent (in the '094 Patent) and 0.01-2M buffering agent (in the '540 Patent), and finally to the admission of Dr. Bannister that glacial acetic acid can be used, under certain circumstances, as a solvent. (See Bannister Responsive Dec. at ¶ 22.) Defendants, however, cite no expert or other evidence to buttress their assertion that glacial acetic acid serves as a co-solvent in connection with the patents-in-suit. Nor have they explained away the fact that each exemplar embodiment in the specifications of the patents-in-suit include glacial acetic acid in an amount too insignificant for it to function as a co-solvent. (See, e.g., '094 Patent at 3:3-4:67; Bannister Responsive Dec. at ¶ 22 (explaining that although glacial acetic acid "can be used as a solvent in certain synthetic- and analytical-chemistry applications," the "Examples of the patents-in-suit" claim "simply too little [glacial] acetic acid for it to act as a co-solvent").) Beyond this initial deficiency, Defendants' position proves inconsistent with the specifications' own description of "glacial acetic acid" as a "buffering agent." ('094 Patent at 3:20; '540 Patent at 4:25.) Indeed, the

Opening Dec. at ¶¶ 22, 64; see also Bannister Responsive Dec. at ¶ 18.) Indeed, Dr. Bannister explained that a solution isn't aqueous if it uses a solvent other than water.[27]

The extrinsic sources identified, and relied upon, by the parties then lend further consistent support to this construction. Indeed, essentially every extrinsic source identified by the parties in the pending Markman submissions (and in their Joint Claim Construction and Prehearing Statement) defines "aqueous solution" in the manner Baxter proposes – "a solution with the solvent as water."[28] (See, e.g., Exs. 10-14 to

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specification of the '540 Patent states, on its face, that the "combination of sodium acetate and glacial acetic acid" works as a "buffering agent," i.e., the excipient that stabilizes the pH balance of the aqueous solution. ('540 Patent at 3:8-10.) As a result, the Court finds no convincing support for Defendants' position that glacial acetic acid serves as a co-solvent in the claimed esmolol formulations. Nor does the Court conclude that Baxter's proposed construction – the one that will be adopted by this Court – creates any "unnecessary ambiguity or confusion." (Defs.' Opening Br. at 14.) To the contrary, the construction relies upon the commonplace concept of a solvent, and would require, at least to the ordinary artisan, no additional elaboration. (See, e.g., Bannister Opening Dec. at ¶ 65 n.8 (explaining, in a footnote, the commonplace concept of a solvent).)

[27] During the Markman hearing, Baxter walked the Court through the various sections of *Remington: The Science and Practice of Pharmacy* that equally reflect that understanding.

[28] During the Markman hearing, Defendants restated their reliance upon the more general definition of "aqueous," as contained within the extrinsic sources identified by Baxter. Nevertheless, because Defendants do not genuinely dispute that the phrase "aqueous" pharmaceutical composition ultimately contemplates an "aqueous" solution, the more generic definitions of "aqueous" carry minimal weight, particularly in view of the more specific definitions for the phrase "aqueous solution."

Goldberg Opening Dec.; Exs. A & B to Devine Opening Dec.) The *McGraw Hill Dictionary of Scientific and Technical Terms* (cited by Baxter), the *McGraw Hill Dictionary of Chemistry* (cited by Baxter), the *Academic Press Dictionary of Science and Technology* (cited by Baxter and Defendants), for example, each expressly endorse this definition.[29] (See, e.g., Ex. 10 to Goldberg Opening Dec. at 120 (defining "aqueous solution" as "[a] solution with the solvent as water); Ex. 11 to Goldberg Opening Dec. at 28 (same); Ex. 12 to Goldberg Opening Dec. at 142 (defining "aqueous solution" as "[a] solution with water as the solvent").)

For all of these reasons, the Court construes the term "aqueous" pharmaceutical composition as "a solution in which water acts as the solvent."

[29] Aside from pointing to the definitions of "aqueous" in Baxter's sources, Defendants rely, in their own right, upon two extrinsic sources. More specifically, Defendants look to the definition of "aqueous" in cite the *Academic Press Dictionary of Science and Technology* (all while ignoring the more-specific definition of "aqueous solution") and the *Concise Chemical and Technical Dictionary*. (See Defs.' Opening Br. at 13 (citing Ex. A to Devine Opening Dec. (defining "aqueous" as a "[w]ater solution"); Ex. B to Devine Opening Dec. (defining "aqueous" as "*Science*. Of or relating to water. *Chemistry*. of a solution, containing water" and "aqueous solution" as "a solution with water as the solvent")); Defs.' Responsive Br. at 13.) Nevertheless, because these sources fail to narrow in on the concept relevant here – an aqueous solution – neither resource (at least in the way relied upon by Defendants) proves particularly instructive for purposes of claim construction.

D. Injectable, aqueous pharmaceutical composition

In terms of defining the phrase "injectable, aqueous pharmaceutical composition," as used only in the '094 Patent, the parties advance the following competing constructions:

Baxter's Proposed Construction	Defendants' Proposed Construction
a stable, ready-to-use aqueous parenteral solution which has been subjected to autoclaving	~~Plain and ordinary meaning~~ **-or-** injectable pharmaceutical composition containing water

More specifically, Baxter argues that the claimed "injectable, aqueous pharmaceutical composition" must be (1) "stable," (2) "ready-to-use," and (3) "subjected to autoclaving," because these attributes, or features, capture the essence of the claimed invention's novelty over prior art compositions. (Baxter's Responsive Br. at 16-22.) In other words, in its proposed construction, Baxter urges the Court to look to the teachings of the specification, and to incorporate the "clearly and unequivocally" described characteristics into the construction of the claim phrase "injectable, aqueous pharmaceutical composition." (Baxter's Opening Br. at 15-19.) Defendants, by contrast, claim that Baxter's construction "mudd[ies]" the meaning of the claim phrase by impermissibly importing limitations from the specification into an otherwise "straightforward" claim phrase. (Defs.' Opening Br. at 16-17;

Defs.' Responsive Br. at 13-18.) For that reason, Defendants stake out instead a construction that clarifies the definition of the claim term "aqueous" (built upon their now rejected construction), but leaves the claim phrase otherwise undefined. (Defs.' Opening Br. at 16; Defs.' Responsive Br. at 13-18.)

Claim construction "'begins and ends in all cases with the actual words of the claim,'" Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (citation omitted), and fundamental principles of claim construction counsel against incorporation claim limitations from the written description. See, e.g., UltimatePointer, L.L.C. v. Nintendo Co., ___ F.3d ____, 2016 WL 798354, at *4 (Fed. Cir. Mar. 1, 2016) (citing Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1370 (Fed. Cir. 2008));[30] Phillips, 415 F.3d at 1320 (explaining that courts must avoid "one of the cardinal sins of patent law—reading a limitation from the written description into the claims"). Nevertheless, the specification may make clear that the claimed invention has a narrower scope than otherwise implied by the claim language. See Pacing, 778 F.3d at 1024 (citations omitted). The Federal

[30] By letter dated March 9, 2016, Baxter advised this Court of the Federal Circuit's recent, and instructive, decision in UltimatePointer. [See, e.g., Docket Item 95 in 14-7094.]

Circuit has, in turn, determined that the specification limited claim scope, based upon

1. "clear and unmistakable statements" that limit the claims, such as "'the present invention includes ...' or 'the present invention is ...' or 'all embodiments of the present invention are...;'"
2. direction in the specification that the "'successful manufacture'" requires a particular step;
3. an indication that the invention operated by 'pushing (as opposed to pulling) forces,' and then characterized the 'pushing forces' as 'an important feature of the present invention;'"
4. repeatedly derogatory statements which labeled an embodiment as "'antiquated,' having 'inherent inadequacies,' and then detailed the 'deficiencies [that] make it difficult' to use;" and
5. a description of a particular feature as a "'very important'" aspect of the invention, particularly in view of the less beneficial alternatives.

Id. at 1024-25 (citations omitted). With that guidance, this Court must determine whether the three characteristics identified by Baxter limit claim scope (as Baxter argues), or simply serve as limitations distinct from the "injectable, aqueous pharmaceutical composition" (as Defendants claim).

With respect to the "stable" and "ready-to-use" aspects of the claimed invention, however, the specification readily supports the inclusion of these features within the construction of the claim phrase "injectable, aqueous pharmaceutical composition." Indeed, the patentees entitled the '094 Patent

"**READY-TO-USE ESMOLOL SOLUTION**" ('094 Patent at Title (emphasis in original)), and then defined that solution by reference to its stable and ready-to-use aspects throughout the following sequential portions of the specification:

Abstract	explaining that the '094 Patent claims "a ready-to-use injectable, aqueous pharmaceutical composition for the treatment of cardiac conditions" (id. at Abstract (emphasis added))
Background of the Invention	describing the instability and dilution errors associated with prior art esmolol formulations (see id. at 1:31-55) explaining that the prior art left open "a need for a ready-to-use large volume parenteral esmolol hydrochloride that is microbiologically safe and stable in vitro during storage" (id. at 1:56-58 (emphases added))
Summary of the Invention	"The present invention relates to a ready-to-use injectable, aqueous pharmaceutical composition" (id. at 1:5-7 (emphases added))
Detailed Description of the Invention	"The present invention provides a stable, ready-to-use parenteral solution containing esmolol hydrochloride..." (id. at 1:62-65 (emphases added)) "The present invention is stable against hydrolytic degradation..." (id. at 2:2-3 (emphases added))

	"The product is a ready-to-use infusion which can be used directly..." (id. at 2:5-7 (emphases added))
Examples	describing "the preparation of ready-to-use infusion bags of the present invention containing 10 mg/ml esmolol HCl solution" (id. at 2:64-66) (emphases added))

In that way, the specification contains ample indications that the patentee intended the "stable" and "ready-to-use" aspects of the claimed invention to be limiting. Indeed, the language of the specification squarely matches the circumstances identified by the Federal Circuit as limiting claim scope, because the disclosure repeatedly defines the "present invention" or "product" as stable and ready-to-use, **and** disparages the instability and dilution requirement (or, non-ready-to-use preparation) of prior art esmolol compositions. This Court can scarcely imagine disclosures more concise and unequivocal than expressed in the specification of the '094 Patent. For that reason, will incorporate "stable"[31] and "ready-

[31] Defendants take the position that the specification refers to the concept of "stability" in three different contexts, i.e., as being "stable against hydrolytic degradation," as having a "stability in water affected by pH," and as having stability "during autoclaving." (Defs.' Opening Br. at 17-18.) Based upon their view that the specification "present[s] various and differing discussions of stability," Defendants claim "that such a limitation should not be read into the claims." (Id. at 18 (citation and emphasis omitted).) Defendants' position,

to-use"[32] into the construction of the claim phrase "injectable, aqueous pharmaceutical composition."[33]

With respect to the notion that the claimed invention be "subjected to autoclaving," however, the Court reaches a different conclusion. The Court recognizes, at the outset, that

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however, rests upon an overly narrow reading of the written disclosure. Indeed, a cursory inspection of the specification makes plain that it refers only to the instability of the esmolol hydrochloride molecule "in an aqueous environment because of [its] extreme susceptibility to hydrolytic degradation," and not in three distinct contexts. ('094 Patent at 1:31-33.) Stated differently, the specification uniformly refers to the concept of "stability" in terms of highlighting the stability of the claimed formulations in water-based environments (and by contrast to the prior art).

[32] During the Markman hearing, and briefly in their Markman submissions, Defendants argued that the phrase "injectable, aqueous pharmaceutical composition" cannot be construed to include a "ready-to-use" limitation, because the specification, at certain points, uses the terms "injectable" and "ready-to-use" in the same sentence. (Defs.' Opening Br. at 18; see also Defs.' Responsive Br. at 15.) In other words, Defendants take the position that "injectable" and "ready-to-use" cannot be read in tandem, because the "ready-to-use" aspect of the claimed invention is necessarily imbedded within the claim limitation "injectable." Nevertheless, the specification, as illustrated above, reflects that the ready-to-use nature of the compositions constitutes a distinct feature of the "present invention" (see, e.g., '094 Patent at 2:5-7), and never uses the term "injectable" to describe the "present invention" of the '094 Patent. Beyond that, Defendants have identified no convincing intrinsic support for the notion that the two concepts cannot be read together.

[33] In arguing against the inclusion of "ready-to-use," Defendants urge the Court to look to the teachings of the '540 Patent. (See, e.g., Defs.' Opening Br. at 6.) Nevertheless, because the '540 Patent nowhere recites the word "injectable" and includes, in any event, disclosures beyond that taught and claimed in the '094 Patent, Defendants' reliance upon the '540 Patent misses the mark.

the ’094 Patent touts the amenability of its esmolol solution to terminal sterilization via autoclaving. Indeed, as with its description of the terms “stable” and “ready-to-use,” the specification states that prior art formulations could not survive autoclaving, and therefore required aseptic sterilization. (See ’094 Patent at 1:40-47, 2:1-2.) By contrast, “[t]he present invention provides a stable, ready-to-use parenteral solution . . . [that] **can be** packaged in a sealed container and subjected to terminal sterilization via autoclaving to reduce the microbiological burden of the formulation.” (Id. at 1:66-2:1 (emphasis added).) The specification then states that “[t]he esmolol hydrochloride composition[s] of the present invention **can be** autoclaved at a temperature ranging from 115 to 130°C. for a period of time ranging from 5 to 40 minutes with acceptable stability.” (Id. at 2:53-56 (emphasis added).) This sterilization process, in turn, results in a microbiologically safer, and pharmaceutically acceptable, esmolol composition than could ordinarily be obtained through aseptic handling. (See generally id. at 1:60-2:58.) In other words, the novelty of the invention claimed by the ’094 Patent hinges, in large part, upon the ability of the esmolol formulation to withstand terminal sterilization by autoclaving. (See generally id.)

Based upon that understanding, and these references in the specification, Baxter argues that the phrase "injectable, aqueous pharmaceutical composition" should be construed to include the requirement that the composition be "'subjected to autoclaving.'" (Baxter's Responsive Br. at 20-22.) The statement in the specification that the composition "**can be** autoclaved," however, less closely resembles the language the Federal Circuit looks for in finding specification language limiting for claims construction purposes, and unlike the references to "stable" and "ready-to-use," the specification does not incorporate the autoclaving references into the clear expression (or, definition) of the "present invention." Thus, although the written disclosure endorses the notion that the novelty of the '094 Patent flows, at least in part, from the suitability of the claimed composition to autoclaving, the language of the specification lends itself equally to the premise that autoclaving constitutes the preference among other available sterilization techniques.[34] Stated differently, the Court cannot conclude that the specification contains an

[34] Although the '540 Patent expands the scope of compositions claimed in the '094 Patent, the Court finds it noteworthy that the '540 Patent recognizes that the pharmaceutical compositions claimed in that continuation-in-part patent can be sterilized in ways other than autoclaving, and specifically states that "sterile pharmaceutical compositions according to the present invention may be prepared using aseptic processing techniques." ('540 patent 3:65-4:1.)

explicit statement that the claimed composition must be subjected to autoclaving.

Further, such a construction ultimately proves irreconcilable with claim 4 of the '094 Patent. Claim 4 is specifically directed at a "method for preparing a sterile, injectable aqueous pharmaceutical composition ... [that has been] autoclav[ed] for a period of time sufficient to render the composition sterile." ('094 Patent at 6:1-9 (emphasis added).) Composition claim 1, by contrast, claims an "injectable, aqueous pharmaceutical composition" with specified ranges of the component ingredients, but with no provision for sterilization by autoclaving. (Id. at 5:8-17 (emphasis added).) Baxter's proposal to incorporate "subjected to autoclaving" into claim 1 would, in turn, fail to give proper effect to claim 4. Indeed, such a construction would render the latter portions of claim 4 redundant and superfluous, and would require reliance upon a strongly disfavored approach to claims construction.[35] See, e.g., Atlas IP, LLC v. Medtronic, Inc., 809 F.3d 599, 607 (Fed. Cir. 2015) (explaining that established convention "counsels

[35] Although Baxter argues that the Court should, in essence, ignore the surplusage in claim 4, Baxter points to no convincing support for this proposition, and instead relies only upon more generalized proposition that cannons of construction can, under certain circumstances, be relaxed. (See Baxter's Responsive Br. at 22 (citations omitted).) Aside from this deficiency, the Court has, as recounted above, found no unequivocal expression that requires the inclusion of "subjected to autoclaving."

against constructions that render some claim language superfluous"); Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); Power Mosfet Techs., L.L.C. v. Siemens AG, 378 F.3d 1396, 1410 (Fed. Cir. 2004) (explaining the "generally disfavored" nature of a claim construction that renders claim terms superfluous). Against that backdrop, the Court cannot find the "subjected to autoclaving" feature limiting for purposes of claim construction.

Beyond the intrinsic realities of the '094 Patent, Baxter's own expert, Dr. Bannister, acknowledged that the words "injectable[,] aqueous pharmaceutical composition" do not, by themselves, imply "autoclaving" to a person of ordinary skill. (Bannister Dep. at 130:24-131:3.) In other words, Dr. Bannister essentially admitted that any importation of "autoclaving" would be inconsistent with the relevant ordinary understanding of the claim language. (Id.) Dr. Bannister's statement, in turn, lends further support to the notion that the claim phrase should not be construed to include the "autoclaving" feature.

For all of these reasons, the Court construes the phrase "injectable, aqueous pharmaceutical composition" as "a stable, ready-to-use aqueous parenteral solution."

V. CONCLUSION

An accompanying Markman Order will be entered in these related patent infringement actions.

April 5, 2016
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge